EPA REGISTRATION NUMBER 71806-1 – VOLUME 1

FQPA

SUBMISSION BAR CODE # 5577795 REVIEWER K. Leavy-Munk

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 71806-1 PM 33 ACTION CODE 302

DESCRIPTOR Amended Labeling

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
03 24 00	03 27 00	03 29 00

METHOD OF SUPPORT

[ ] CITE-ALL
[ ] SELECTIVE
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

FORMULATORS EXEMPTION

[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER _____				

STATUS _____

RESPONSE CODE 12 RESPONSE DATE MAY 09 2000

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAY 0 9 2000

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Plant Cell Technology, Inc.
1920 North Street, NW
Washington, D.C. 20036

Attention: Ana Rodriguez-Koster

Subject: PPM
EPA Registration Number 71806-1
Your Submission Dated March 24th, 2000
EPA Received Date March 27th, 2000

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to expand the "Directions for Use" to provide users with detailed instructions for different cultures scenarios, is unacceptable.

The product mentioned above is neither a disinfectant nor a sterilant, but a microbiocide for use in the control of non-pathogenic organisms. Use of the terms " to disinfect" or "to sterilize" are associated with the control of human health pathogens and requires the submission of efficacy data.

Submit five (5) copies of draft labels revised in accordance with the following instructions:

A. Change "....prior to sterilization with PPM" under section 6(a) to read ".....prior to treatment with PPM....".

B. Change "...following the sterilization with PPM",..." under section 8(b) to read "....following treatment with PPM...".

C. Change "....to disinfect endogenous contamination...." and ".....to disinfect 'in-culture' contamination" under section 8(b) to read"...to control endogenous contamination...." and "....to control 'in-culture' contamination.'"

D. In section 10, change ".... get rid of the endogenous..." to read ".... to control endogenous organisms....".

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7505C)

A

B

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

HAND DELIVERED

March 24, 2000

Office of Pesticide Programs
Antimicrobial Division
Document Processing Desk [AMEND]
Room 258, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

ATTENTION: ***Marshall Swindell***
Product Manager, Team 33

SUBJECT: ***Plant Cell Technology, Inc.***
PPM (EPA Reg. No. 71806-1)
Label Amendment to expand the "Directions for Use" to provide users with detailed instructions for different culture scenarios

Dear Mr. Swindell:

As agent for Plant Cell Technology, Inc., we are submitting a pesticide amendment to expand the instructions under the "Directions for Use" section of their product, ***PPM*** **(EPA Reg. No. 71806-1)**. These additional instructions will provide users with further details as to how to use the product under different culture scenarios. Please note that Plant Cell Technology, Inc. is ***not*** changing or adding new uses to ***PPM***, but only expanding user instructions to accommodate for the correct usage of ***PPM*** under different culture scenarios. The uses appearing on the proposed label have been previously approved for the ***PPM*** registration. Therefore, there is no need to submit any data or cite any data for this amendment.

Enclosed, please find the following documents to support this label amendment:

1) Application for Pesticide Amendment (OPP ID No. 256720);
2) Five (5) copies of the proposed product labeling

Insofar as Lewis & Harrison is the authorized "Contact Point" and "Company Agent" for Plant Cell Technology, Inc, please relay all correspondence directly to us. If you have any questions, please contact me at 202-393-3903.

Thank you very much for your cooperation in this matter.

Sincerely,

Ana Rodriguez-Koster

Ana Rodriguez-Koster
Agent for Plant Cell Technology, Inc.

Enclosures

cc: Martin Kalin (Plant Cell Technology, Inc.)

Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ **Registration** X **Amendment** ☐ **Other:**

OPP Identifier Number: 256720

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71806-1	**Marshall Swindell**	X None ☐ Restricted
4. Company/Product (Name) **PPM**	PM# **Team 33**	

5. Name and Address of Applicant *(Include ZIP Code)*
Plant Cell Technology, Inc.
1920 N Street, NW
Washington, DC 20036
PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW
☐ *Check if this is a new address*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

X Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Label Amendment to expand the "Directions for Use" to provide users with detailed instructions for different culture scenarios

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
***Certification must be submitted**	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Ana Rodriguez-Koster, Lewis & Harrison, LLC, 122 C St. NW, Ste. 740, Washington, DC 20001	**Agent for Plant Cell Technology, Inc.**	**202-393-3903**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Ana Rodriguez-Koster	**Agent for Plant Cell Technology, Inc.**	
4. Typed Name **Ana Rodriguez-Koster**	5. Date ***March 24, 2000***	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete White- EPA File Copy (original) Yellow- Applicant Copy

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Use rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED: Call a physician or poison control center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
PPM is a broad-spectrum preservative and biocide. *PPM*™ is an excellent preservative agent that can be used in research and commercial laboratories to inhibit growth of, or kill bacteria and fungi in plant tissue culture growth media. It targets fundamental enzymes in the Krebs cycle and in the Electron Transport Chain. Depending on the dose level, *PPM* is both biocidal (>2ml/L of media) and biostatic (<2ml/L of media). When diluted with plant growth media (5-10 ml/L *PPM*/liter growth media is effective as a microbiocide against non-human health pathogenic organisms.

1. Media containing *PPM*™ may be dispensed outside the laminar flow hood (LFH) exposed to the ambient air. The plates should be covered soon after agar solidification. In the event a pump dispenses the media, we recommend passing autoclaved hot water through the hoses before and after dispensing media.

2. Heat sensitive or heat stable liquid media containing *PPM*™ do not need to be sterilized by Millipore filters or

PPM

Preservative for Plant Tissue Culture Media

ACTIVE INGREDIENTS:
5-Chloro-2-methyl-3(2H)-isothiazolone...0.1350%
2-methyl-3(2H)-isothiazolone.....0.0412%
INERT INGREDIENTS.....99.8238%

KEEP OUT OF REACH OF CHILDREN
CAUTION
EPA Reg. No. 71806-1 EPA EST NO. 71806-NJ-1

autoclaved provided that it will be stored in sterile containers and that the stock solutions are not previously contaminated. In rich media containing 200 mg/liter or more of amino acids or proteins, it is recommended to filter the media with the *PPM*™.

3. Working in the LFH the utensils (forceps or scalpels) do not need to be flamed. They may be periodically dipped in 70% alcohol. The LFH does not need to be certified and the work can also be done outside the LFH on a clean surface for a period not exceeding 1 hour.

4. *PPM*™ comes in an acidic liquid solution (pH 3.8) and should be stored at 4°C. The recommended dose is 0.5 – 2.0 ml of *PPM*™ per liter of medium (0.05 – 0.2% V/v) added before or after autoclavation to prevent airborne and endogenous contamination at low inoculum densities. Higher doses are required to treat endogenous contamination or to obtain Agrobacteria free plant material.

5. *PPM*™ is less effective when exposed to high density of bacteria or fungi spores found regularly on a seed's coat. For *in vitro* germination, seeds should be conventionally surface sterilized with EPA registered bleach. Therefore, in the presence of *PPM*™ (in the germination medium), the seeds can be rinsed under tap water in a non-sterile strainer and left to dry preferably in the LFH. Protoplast isolation solution should be sterilized mechanically through Millipore filters with the *PPM*. If the utensil ends have touched active bacteria, fungi culture or otherwise suspected of being contaminated, they should be sterilized by autoclave or by use of an electric heating element.

6. Endogenous Contamination:

To eliminate high-density endogenous contamination, higher doses of PPM™ are required.

(a) For seeds: stir non-sterilized seeds for 8 to 12 hours in 1-2% PPM™ solutions (v/v) supplemented with 50 mg/l Magnesium salt (Magnesium Chloride, Magnesium Sulfate or Magnesium Nitrate). Subsequently, without rinsing, transfer to germination medium supplemented with 0.05 – 0.1% PPM™ for herbaceous plants and 0.2% PPM™ for woody plants. Hard-coated seeds (e.g., Asparagus, Lupine, Ornamental Palm, Rose, etc.) should be soaked in water for 2-4 hours prior to sterilization with NO PPM™.

(b) For explants: gently shake / stir 1 cm. long explants (or shorter) in bleach solution routinely to remove surface contamination. Rinse with water (can be done under non-sterile conditions), and shake / stir for 8-12 hours in 1 – 2 % PPM™ solution supplemented with 50 mg/l Magnesium salt (see paragraph 6(a) above). Without rinsing, insert into a medium supplemented with 0.05 – 0.1% PPM™ for herbaceous plants and 0.2 ml/l PPM™ for woody plants. Expose the plates to low light intensities for the first 5 days.

(c) For tubers, bulbs and scales: shake / stir the entire tuber / bulb / scale in bleach routinely. Rinse with water (can be done under non-sterile conditions). Slice the tuber / bulb / scale to thin slices. Shake / stir for 8 – 12 hours in 2 –5% PPM™ solution supplemented with 50 mg/l Magnesium salt (see paragraph 6(a) above). Without rinsing, place on a proper medium containing 0.1 – 0.2% PPM™. Expose the plates to low light intensities for the first 5 days.

(For use in the United States this applies only to woody plants and explants and ornamental plants and explants)

7. In cases where the above procedures do not yield satisfying results (e.g., thick explants, highly infested explants, seeds) we recommend the following:

(a) Shake / stir the explants in water (1 hr / 2 hrs for soft / hard tissues, respectively)

(b) Shake / stir the explants in half strength (50% v/v) PPM™ (diluted with sterile water) for 10-30 minutes.

(c) Without rinsing, insert the explants into the medium. Expose the plates to low light intensities for the first 10 days. With fungal contamination, the addition of PPM™ to the medium is optional. With bacterial or mixed contamination, the addition of 0.05 – 0.2% PPM™ to the medium is essential during the first month. Do not discard highly oxidized explants. Approximately 50% of the explants will recover within 4 – 6 weeks.

Note:
Refer to notes 3 and 4 in paragraph 8 below

8. To decontaminate "in culture" contaminated plant material (rescue treatment):

Note: The culture should not be left visibly contaminated longer than one week.

(a) Clean the material mechanically using a soft toothbrush under a stream of tap water. Shake / stir in a 50% PPM™ solution (diluted with sterile water) for 15-30 minutes. For bacterial or mixed contamination we recommend to lower the solution pH to the range of 2.8 – 3.2 by mixing 1:1 full strength PPM™ (100%) with 0.6 gr/liter Citric acid solution (use sterile water).

(b) Without rinsing insert into a medium with 0.05 – 0.2% PPM™ for at least one month. Keep the culture away from high light intensities for the first 10 days. Wait 4-6 weeks before discarding oxidized explants.

Notes:

1. When transferring the explants, following the sterilization with PPM™, we recommend to insert the explants entirely into the medium. For better contact, prepare a semi-solid medium.

2. The 50% PPM™ solution can be reused approximately 10 times. The number of uses depends on the volume of the explants treated and the inoculum density. Keeping the 50% PPM™ solution stored at 4°C will prolong its activity. If necessary, prepare two PPM™ solutions: one to disinfect endogenous contamination and the second, to disinfect "in-culture" contamination. The second solution should be filtered after each treatment, using a 0.4 micrometer Millipore. The filtration process can be done in non-sterile atmosphere. A single filter can be used for the entire "lifespan" of the solution.

9. To eliminate Agrobacterium:

After co-cultivation, rinse the leaf discs with plenty of water, with the aid of a strainer. Dip the transfected discs in 50-100% PPM™ solution for 2 – 5 minutes. Blot the discs between two sterile paper towels and place onto a medium supplemented with either full-strenght routinely-used antibiotics, 0.05 – 0.1% PPM™, or a combination of 0.05 – 0.1% PPM™ with 25 – 50% of the routinely used dose of antibiotics.

10. For Protoplast:

Add PPM™ 0.05-0.1% only when cell divisions commenced. If the protoplasts source material has systemic contamination, get rid of the endogenous (see paragraph 6 above) and then isolate the protoplasts. The addition of 0.05-0.1% PPM™ after cell division is only to prevent airborne derived contamination.

Anther's and microscopes' cultures like protoplasts are sensitive at the beginning to any functional dose of PPM™, therefore, follow the above procedure described for protoplasts.

PPM™ can be added at 0.1% into freshly made stock solutions to keep them clear.

It is up to the researchers to determine the optimal combination of *PPM* doses and time exposure. Different plant types and different explant sources are highly varied in their response to *PPM*.

Storage: Ideal storage temperature is 39°F (4°C). Do not store at temperatures in excess of 70°F (21°C).

Pesticide Disposal: Do not contaminate water, food, or feed by storage and disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

NET CONTENTS:

100 / 150 / 200 / 250 / 300 / 400 / 500 / 1000 / 2000 ml.

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Use rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED: Call a physician or poison control center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat. If person is unconscious, do not give anything by mouth and do not induce vomiting.
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autoclaved provided that it will be stored in sterile containers and that the stock solutions are not previously contaminated. In rich media containing 200 mg/liter or more of amino acids or proteins, it is recommended to filter the media with the *PPM*™.

3. Working in the LFH the utensils (forceps or scalpels) do not need to be flamed. They may be periodically dipped in 70% alcohol. The LFH does not need to be certified and the work can also be done outside the LFH on a clean surface for a period not exceeding 1 hour.

4. *PPM*™ comes in an acidic liquid solution (pH 3.8) and should be stored at 4°C. The recommended dose is 0.5 – 2.0 ml of *PPM*™ per liter of medium (0.05 – 0.2% V/v) added before or after autoclavation to prevent airborne and endogenous contamination at low inoculum densities. Higher doses are required to treat endogenous contamination or to obtain Agrobacteria free plant material.

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Storage: Ideal storage temperature is 39°F (4°C). Do not store at temperatures in excess of 70°F (21°C).

Pesticide Disposal: Do not contaminate water, food, or feed by storage and disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

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5. *PPM*™ is less effective when exposed to high density of bacteria or fungi spores found regularly on a seed's coat. For *in vitro* germination, seeds should be conventionally surface sterilized with EPA registered bleach. Therefore, in the presence of *PPM*™ (in the germination medium), the seeds can be rinsed under tap water in a non-sterile strainer and left to dry preferably in the LFH. Protoplast isolation solution should be sterilized mechanically through Millipore filters with the *PPM*. If the utensil ends have touched active bacteria, fungi culture or otherwise suspected of being contaminated, they should be sterilized by autoclave or by use of an electric heating element.

6. Endogenous Contamination:

To eliminate high-density endogenous contamination, higher doses of PPM™ are required.

(a) For seeds: stir non-sterilized seeds for 8 to 12 hours in 1-2% PPM™ solutions (v/v) supplemented with 50 mg/l Magnesium salt (Magnesium Chloride, Magnesium Sulfate or Magnesium Nitrate). Subsequently, without rinsing, transfer to germination medium supplemented with 0.05 – 0.1% PPM™ for herbaceous plants and 0.2% PPM™ for woody plants. Hard-coated seeds (e.g., Asparagus, Lupine, Ornamental Palm, Rose, etc.) should be soaked in water for 2-4 hours prior to sterilization with PPM™.

(b) For explants: gently shake / stir 1 cm. long explants (or shorter) in bleach solution routinely to remove surface contamination. Rinse with water (can be done under non-sterile conditions), and shake / stir for 8-12 hours in 1 – 2 % PPM™ solution supplemented with 50 mg/l Magnesium salt (see paragraph 6(a) above). Without rinsing, insert into a medium supplemented with 0.05 – 0.1% PPM™ for herbaceous plants and 0.2 ml/l PPM™ for woody plants. Expose the plates to low light intensities for the first 5 days.

(c) For tubers, bulbs and scales: shake / stir the entire tuber / bulb / scale in bleach routinely. Rinse with water (can be done under non-sterile conditions). Slice the tuber / bulb / scale to thin slices. Shake / stir for 8 – 12 hours in 2 –5% PPM™ solution supplemented with 50 mg/l Magnesium salt (see paragraph 6(a) above). Without rinsing, place on a proper medium containing 0.1 – 0.2% PPM™. Expose the plates to low light intensities for the first 5 days.

(For use in the United States this applies only to woody plants and explants and ornamental plants and explants)

7. In cases where the above procedures do not yield satisfying results (e.g., thick explants, highly infested explants, seeds) we recommend the following:

(a) Shake / stir the explants in water (1 hr / 2 hrs for soft / hard tissues, respectively)

(b) Shake / stir the explants in half strength (50% v/v) PPM™ (diluted with sterile water) for 10-30 minutes.

(c) Without rinsing, insert the explants into the medium. Expose the plates to low light intensities for the first 10 days. With fungal contamination, the addition of PPM™ to the medium is optional. With bacterial or mixed contamination, the addition of 0.05 – 0.2% PPM™ to the medium is essential during the first month. Do not discard highly oxidized explants. Approximately 50% of the explants will recover within 4 – 6 weeks.

Note:
Refer to notes 3 and 4 in paragraph 8 below

8. To decontaminate "in culture" contaminated plant material (rescue treatment):

Note: The culture should not be left visibly contaminated longer than one week.

(a) Clean the material mechanically using a soft toothbrush under a stream of tap water. Shake / stir in a 50% PPM™ solution (diluted with sterile water) for 15-30 minutes. For bacterial or mixed contamination we recommend to lower the solution pH to the range of 2.8 – 3.2 by mixing 1:1 full strength PPM™ (100%) with 0.6 gr/liter Citric acid solution (use sterile water).

(b) Without rinsing insert into a medium with 0.05 – 0.2% PPM™ for at least one month. Keep the culture away from high light intensities for the first 10 days. Wait 4-6 weeks before discarding oxidized explants.

Notes:

1. When transferring the explants, following the sterilization with PPM™, we recommend to insert the explants entirely into the medium. For better contact, prepare a semi-solid medium.

2. The 50% PPM™ solution can be reused approximately 10 times. The number of uses depends on the volume of the explants treated and the inoculum density. Keeping the 50% PPM™ solution stored at 4°C will prolong its activity. If necessary, prepare two PPM™ solutions: one to disinfect endogenous contamination and the second, to disinfect "in-culture" contamination. The second solution should be filtered after each treatment, using a 0.4 micrometer Millipore. The filtration process can be done in non-sterile atmosphere. A single filter can be used for the entire "lifespan" of the solution.

9. To eliminate Agrobacterium:

After co-cultivation, rinse the leaf discs with plenty of water, with the aid of a strainer. Dip the transfected discs in 50-100% PPM™ solution for 2 – 5 minutes. Blot the discs between two sterile paper towels and place onto a medium supplemented with either full-strenght routinely-used antibiotics, 0.05 – 0.1% PPM™, or a combination of 0.05 – 0.1% PPM™ with 25 – 50% of the routinely used dose of antibiotics.

10. For Protoplast:

Add PPM™ 0.05-0.1% only when cell divisions commenced. If the protoplasts source material has systemic contamination, get rid of the endogenous (see paragraph 6 above) and then isolate the protoplasts. The addition of 0.05-0.1% PPM™ after cell division is only to prevent airborne derived contamination.

Anther's and microscopes' cultures like protoplasts are sensitive at the beginning to any functional dose of PPM™, therefore, follow the above procedure described for protoplasts.

PPM™ can be added at 0.1% into freshly made stock solutions to keep them clear.

It is up to the researchers to determine the optimal combination of *PPM* doses and time exposure. Different plant types and different explant sources are highly varied in their response to *PPM*.

Storage: Ideal storage temperature is 39°F (4°C). Do not store at temperatures in excess of 70°F (21°C).

Pesticide Disposal: Do not contaminate water, food, or feed by storage and disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

NET CONTENTS:

100 / 150 / 200 / 250 / 300 / 400 / 500 / 1000 / 2000 ml.

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Use rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED: Call a physician or poison control center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
PPM is a broad-spectrum preservative and biocide. *PPM*™ is an excellent preservative agent that can be used in research and commercial laboratories to inhibit growth of, or kill bacteria and fungi in plant tissue culture growth media. It targets fundamental enzymes in the Krebs cycle and in the Electron Transport Chain. Depending on the dose level, *PPM* is both biocidal (>2ml/L of media) and biostatic (<2ml/L of media). When diluted with plant growth media (5-10 ml/L *PPM*/liter growth media is effective as a microbiocide against non-human health pathogenic organisms.

1. Media containing *PPM*™ may be dispensed outside the laminar flow hood (LFH) exposed to the ambient air. The plates should be covered soon after agar solidification. In the event a pump dispenses the media, we recommend passing autoclaved hot water through the hoses before and after dispensing media.

2. Heat sensitive or heat stable liquid media containing *PPM*™ do not need to be sterilized by Millipore filters or

PPM

Preservative for Plant Tissue Culture Media

ACTIVE INGREDIENTS:
5-Chloro-2-methyl-3(2H)-isothiazolone...0.1350%
2-methyl-3(2H)-isothiazolone.....0.0412%
INERT INGREDIENTS.....99.8238%

KEEP OUT OF REACH OF CHILDREN
CAUTION
EPA Reg. No. 71806-1 EPA EST NO. 71806-NJ-1

autoclaved provided that it will be stored in sterile containers and that the stock solutions are not previously contaminated. In rich media containing 200 mg/liter or more of amino acids or proteins, it is recommended to filter the media with the *PPM*™.

3. Working in the LFH the utensils (forceps or scalpels) do not need to be flamed. They may be periodically dipped in 70% alcohol. The LFH does not need to be certified and the work can also be done outside the LFH on a clean surface for a period not exceeding 1 hour.

4. *PPM*™ comes in an acidic liquid solution (pH 3.8) and should be stored at 4°C. The recommended dose is 0.5 – 2.0 ml of *PPM*™ per liter of medium (0.05 – 0.2% V/v) added before or after autoclavation to prevent airborne and endogenous contamination at low inoculum densities. Higher doses are required to treat endogenous contamination or to obtain Agrobacteria free plant material.

5. *PPM*™ is less effective when exposed to high density of bacteria or fungi spores found regularly on a seed's coat. For *in vitro* germination, seeds should be conventionally surface sterilized with EPA registered bleach. Therefore, in the presence of *PPM*™ (in the germination medium), the seeds can be rinsed under tap water in a non-sterile strainer and left to dry preferably in the LFH. Protoplast isolation solution should be sterilized mechanically through Millipore filters with the *PPM*. If the utensil ends have touched active bacteria, fungi culture or otherwise suspected of being contaminated, they should be sterilized by autoclave or by use of an electric heating element.

6. Endogenous Contamination:

To eliminate high-density endogenous contamination, higher doses of PPM™ are required.

(a) For seeds: stir non-sterilized seeds for 8 to 12 hours in 1-2% PPM™ solutions (v/v) supplemented with 50 mg/l Magnesium salt (Magnesium Chloride, Magnesium Sulfate or Magnesium Nitrate). Subsequently, without rinsing, transfer to germination medium supplemented with 0.05 – 0.1% PPM™ for herbaceous plants and 0.2% PPM™ for woody plants. Hard-coated seeds (e.g., Asparagus, Lupine, Ornamental Palm, Rose, etc.) should be soaked in water for 2-4 hours prior to sterilization with PPM™.

(b) For explants: gently shake / stir 1 cm. long explants (or shorter) in bleach solution routinely to remove surface contamination. Rinse with water (can be done under non-sterile conditions), and shake / stir for 8-12 hours in 1 – 2 % PPM™ solution supplemented with 50 mg/l Magnesium salt (see paragraph 6(a) above). Without rinsing, insert into a medium supplemented with 0.05 – 0.1% PPM™ for herbaceous plants and 0.2 ml/l PPM™ for woody plants. Expose the plates to low light intensities for the first 5 days.

(c) For tubers, bulbs and scales: shake / stir the entire tuber / bulb / scale in bleach routinely. Rinse with water (can be done under non-sterile conditions). Slice the tuber / bulb / scale to thin slices. Shake / stir for 8 – 12 hours in 2 –5% PPM™ solution supplemented with 50 mg/l Magnesium salt (see paragraph 6(a) above). Without rinsing, place on a proper medium containing 0.1 – 0.2% PPM™. Expose the plates to low light intensities for the first 5 days.

(For use in the United States this applies only to woody plants and explants and ornamental plants and explants)

7. In cases where the above procedures do not yield satisfying results (e.g., thick explants, highly infested explants, seeds) we recommend the following:

(a) Shake / stir the explants in water (1 hr / 2 hrs for soft / hard tissues, respectively)

(b) Shake / stir the explants in half strength (50% v/v) PPM™ (diluted with sterile water) for 10-30 minutes.

(c) Without rinsing, insert the explants into the medium. Expose the plates to low light intensities for the first 10 days. With fungal contamination, the addition of PPM™ to the medium is optional. With bacterial or mixed contamination, the addition of 0.05 – 0.2% PPM™ to the medium is essential during the first month. Do not discard highly oxidized explants. Approximately 50% of the explants will recover within 4 – 6 weeks.

Note:
Refer to notes 3 and 4 in paragraph 8 below

8. To decontaminate "in culture" contaminated plant material (rescue treatment):

Note: The culture should not be left visibly contaminated longer than one week.

(a) Clean the material mechanically using a soft toothbrush under a stream of tap water. Shake / stir in a 50% PPM™ solution (diluted with sterile water) for 15-30 minutes. For bacterial or mixed contamination we recommend to lower the solution pH to the range of 2.8 – 3.2 by mixing 1:1 full strength PPM™ (100%) with 0.6 gr/liter Citric acid solution (use sterile water).

(b) Without rinsing insert into a medium with 0.05 – 0.2% PPM™ for at least one month. Keep the culture away from high light intensities for the first 10 days. Wait 4-6 weeks before discarding oxidized explants.

Notes:

1. When transferring the explants, following the sterilization with PPM™, we recommend to insert the explants entirely into the medium. For better contact, prepare a semi-solid medium.

2. The 50% PPM™ solution can be reused approximately 10 times. The number of uses depends on the volume of the explants treated and the inoculum density. Keeping the 50% PPM™ solution stored at 4°C will prolong its activity. If necessary, prepare two PPM™ solutions: one to disinfect endogenous contamination and the second, to disinfect "in-culture" contamination. The second solution should be filtered after each treatment, using a 0.4 micrometer Millipore. The filtration process can be done in non-sterile atmosphere. A single filter can be used for the entire "lifespan" of the solution.

9. To eliminate Agrobacterium:

After co-cultivation, rinse the leaf discs with plenty of water, with the aid of a strainer. Dip the transfected discs in 50-100% PPM™ solution for 2 – 5 minutes. Blot the discs between two sterile paper towels and place onto a medium supplemented with either full-strenght routinely-used antibiotics, 0.05 – 0.1% PPM™, or a combination of 0.05 – 0.1% PPM™ with 25 – 50% of the routinely used dose of antibiotics.

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NET CONTENTS:

100 / 150 / 200 / 250 / 300 / 400 / 500 / 1000 / 2000 ml.

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

03/29/2000

ANA RODRIGUEZ KOSTA
LEWIS & HARRISON, LLC
122 C STREET, NW, SUITE 740
WASHINGTON DC 20001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: PPM
COMPANY NAME: LEWIS & HARRISON, LLC
OPP IDENTIFICATION NUMBER: 256720
EPA REGISTRATION NUMBER: 71806-1
EPA RECEIPT DATE: 03/27/2000

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Marshall Swindell, Product Manager 33, at (703)-308-6230.

Sincerely,

J Wrose

Front End Processing Staff
Information Services Branch
Program Management and Support Division

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Use rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

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KEEP OUT OF REACH OF CHILDREN
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100 / 150 / 200 / 250 / 300 / 400 / 500 / 1000 / 2000 ml.

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

SUBMISSION BAR CODE # 5559048 REVIEWER Kilcarry-Munx

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 71806-R PM 33 ACTION CODE 185

DESCRIPTOR Argumental Response to Agency's Findings

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
03 / 10 / 99	03 / 15 / 99	03 / 17 / 99

METHOD OF SUPPORT

[X] CITE-ALL
[ ] SELECTIVE
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

FORMULATORS EXEMPTION

[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER _____				

STATUS At the request of the company the review of the new alt. CSF was terminated so that reg. of the basic CSF could occur. MK

RESPONSE CODE 18 RESPONSE DATE APR 16 1999

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7504C)
401 "M" St., S.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_x_ Registration
____ Reregistration

(under FIFRA, as amended)

EPA Reg. Number: 71806-1

Date of Issuance: APR 16 1999

Term of Issuance: Conditional

Name of Pesticide Product: PPM

Name and Address of Registrant (include ZIP Code):

Plant Cell Technology, Inc.
1920 North Street, NW
Washington, D.C. 20036

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

   a. Revise the EPA Registration Number to read, "EPA Reg. No. 71806-1".

   b. The provided Analytical Methods for the active ingredient, referenced under MRID No. 43865202, has been reviewed and found to be acceptable.

   c. The provided product chemistry data in MRID Nos. 445993-01 and 445993-02 provides data for Guideline Series 61, 62, and 63. These data are in compliance with 40 CFR part 158.155 through 158.190. It satisfies product chemistry data for this product.

Signature of Approving Official: Marshall Swindell,
Product Manager 33

Date: APR 16 1999

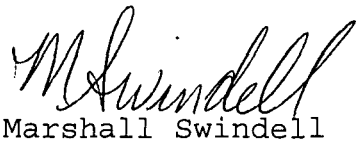
EPA Form 8570-6

The Confidential Statement of Formula dated July 8, 1998, is in compliance with PR Notice 91-2; it agrees with the label and the basic Confidential Statement of Formula, is acceptable.

3. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510W)

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Use rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
PPM is a broad-spectrum preservative and biocide. *PPM* is an excellent preservative agent that can be used in research and commercial laboratories to inhibit the growth of, or kill bacteria and fungi in plant tissue culture growth media. It targets fundamental enzymes in the Krebs cycle and in the Electron Transport Chain. Depending on the dose level, *PPM* is both biocidal (>2ml/L of media) and biostatic (<2ml/L of media). When diluted with plant growth media (5-20 ml/L *PPM*/liter growth media is effective as a microbiocide against non-human health pathogenic organisms.

1. Media containing *PPM* may be dispensed outside the laminar flow hood (LFH) exposed to the ambient air. The plates should be covered soon after agar solidification. In the event a pump dispenses the media, we recommend passing autoclaved hot water through the hoses before and after dispensing media.

2. Heat sensitive or heat stable liquid media containing *PPM* do not need to be sterilized by Millipore filters or autoclaved provided that it will be stored in sterile containers and that the

PPM

Preservative for Plant Tissue Culture Media

ACTIVE INGREDIENTS:	
5-Chloro-2-methyl-3(2H)-isothiazolone.....	0.135%
2-methyl-3(2H)-isothiazolone.....	0.0412%
INERT INGRDIENTS.....	99.8238%

KEEP OUT OF REACH OF CHILDREN
CAUTION
EPA REG. NO. **EPA EST NO.**

stock solutions are not previously contaminated. In rich media containing 200 mg/liter or more of amino acids or proteins, it is recommended to filter the media with the *PPM*.

3. Working in the LFH the utensils (forceps or scalpels) do not need to be flamed. They may be periodically dipped in 70% alcohol. The LFH does not need to be certified and the work can also be done outside the LFH on a clean surface for a period not exceeding 2 - 3 hours.

4. *PPM* comes in an acidic liquid solution (pH 3.8) and should be stored at 4°C. The recommended dose is 0.5 - 2.0 ml of *PPM* per liter of medium. Higher doses are required to treat endogenous contamination or to obtain Agrobacteria free plant material.

5. *PPM* is less effective when exposed to high density of bacteria or fungi spores found regularly on a seed's coat. For *in vitro* germination, seeds should be conventionally surface sterilized with EPA registered bleach. Therefore, in the presence of *PPM* (in the germination medium), the seeds can be rinsed under tap water in a non-sterile strainer and left to dry preferably in the LFH. Protoplast isolation solution should be sterilized mechanically through Millipore filters with the *PPM*. If the utensil ends have touched active bacteria, fungi culture or otherwise suspected of being contaminated, they should be sterilized by autoclave or by use of an electric heating element.

6. *Endogenous Contamination:*

Plant tissue culture media containing *PPM* at doses of 5-20 ml/l can be used to eliminate endogenous contamination in seeds and plant-explants. In such cases, the seeds or the explants should be treated with an EPA registered plant disinfectant. After rinsing with DI water, explants or buds should be embedded or placed in autoclaved semisolid or liquid medium respectively. The proper media such as callus proliferation or regeneration can be used with only ¼ strength of the inorganic salts, supplemented with 5-20 ml/l *PPM*/media mixture. After 2-5 days the explants can be transferred without rinsing into a similar media (full strength inorganic salts) supplemented with at least 0.5 ml/l *PPM*/media mixture at 20-24 degrees centigrade. Seeds can be transferred to germination medium (full strength of inorganic salts) supplemented with 0.5 ml/l *PPM* after 5-10 days.

It is up to the researchers to determine the optimal combination of *PPM* doses and time exposure. Different plant types and different explant sources are highly varied in their response to *PPM*.

Storage and Disposal

Storage: Ideal storage temperature is 39°F (4° C). Do not store at temperatures in excess of 70°F (21°C).

Pesticide Disposal: Do not contaminate water, food, or feed by storage and disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility

Container Disposal: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

NET CONTENTS:

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

ACCEPTED
with COMMENTS
In EPA Letter Dated:

APR 16 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 71806-1

21

LEWIS &
HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

March 10, 1999 ***Hand Delivered***

Office of Pesticide Programs
Antimicrobial Division (7510W)
Document Processing Desk (SWINDELL)
Room 258, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Dear Marshall:

RE: Plant Cell Technologies, Inc., PPM (EPA File Symbol No. 71806-R)
Response to Agency letter dated February 25, 1999

The above referenced letter (copy enclosed – ***Attachment 1***) noted several deficiencies. These deficiencies fall into several main subject areas (product chemistry, administrative requirements, and labeling) each of which are addressed below.

Product Chemistry

Two questions were raised on the product chemistry for PPM. The first question was raised initially in the Agency's letter of November 19th (***Attachment 2***) and concerned the need for an acceptable enforcement method for the active ingredient. We responded by indicating that an acceptable analytical method (EPA MRID No. 4386502) was cited in by permission of the submitter, Lonza – see the original matrix and the enclosed matrix on the new forms. On December 15, 1998, after a conversation with Karen Leavy-Munk, we sent the Agency proof of the acceptability of that method. A copy of that response is enclosed as ***Attachment 3***.

The second question, which was raised in both the November 19th and February 25th correspondence from the Agency, dealt with the level of active ingredient in the alternate formula that we submitted, dated July 8, 1998. Although the level of active ingredients in that alternate formula fell within the certified limits for the basic formula, we have followed the Agency's advise and increased the level of active ingredient to more closely match that of the basic formula. This new CSF is enclosed as ***Attachment 4.*** Because the relative percentages of the two active ingredients in [redacted] differ slightly from the relative percentages in [redacted] it is impossible to obtain an exact match with the basic formula. However, when the Agency registered [redacted] it concluded that it was substantially similar to [redacted] which is the source for the active ingredient in the

Product ingredient source information may be entitled to confidential treatment

basic formula. Further, the level of each active ingredient component in the alternate formula falls well within the certified limits established in the basic formula.

Administrative Documents

Enclosed as ***Attachment 5*** are updated versions of the following forms: Certification with Respect to Citation of Data (EPA Form 8570-34) and the public and the internal Agency review copy of the Data Matrix for the Selective Method of Support (EPA Form 8570-35). As indicated on the matrix, this application is proceeding under the selective method, one all option for certain toxicology data. Additionally, as discussed above, the enforcement analytical method is cited with Lonza's permission. A copy Lonza's letter authorization was included with the original package.

Labeling

All of the requested changes have been made. The one slight variance in the suggested language pertains to where and how the product is to be used (point "c" under labeling). Per our recent discussion, we have added the word commercial so that the sentence now reads, "PPM is an excellent preservative agent that can be used in research and commercial laboratories to inhibit the growth of, or kill bacteria and fungi in plant tissue culture growth media." ***Attachment 6*** contains five copies of revised labeling incorporating all of the suggested changes. For the convenience of the reviewer, we have also included one copy of the label with the changes highlighted. Otherwise, this label is identical to the version included in the original July 8, 1998 application.

Marshall, as we have discussed previously, it is our belief that the intended use of this product does not constitute a "new use" as Congress intended that term. We recognize that the site is a new site; however, the active ingredient is still being used as an indoor non-food use preservative, just as it has always been. Accordingly, anything that you can do to expedite final review and registration of this product will be appreciated. If it would help to speed-up approval, please feel free to address approval of the alternate formula separately from approval of the basic formula.

If any questions remain, please call.

Sincerely,

E. David Lewis
for,
Plant Cell Technology, Inc.

EDL/d

Enclosures

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

FAX COVER SHEET

DATE:	December 15, 1998	**TIME:**	6:37 PM
TO:	Karen Leavy-Munk	**PHONE**	703-308-6237
		FAX	703-308-6467
FROM:	E. David Lewis		
RE:	Plant Cell Technology, Inc. – PPM (EPA File Symbol 71806-R)		

Number of pages including cover sheet: 2

Message

Karen –

[redacted]

I would be happy to wait until after Anna Skapars returns next year to resolve her question on the alternate formula; but if you could issue the basic registration before the end of the year on the basis of the enclosed, we would certainly appreciate it.

Once again, thanks for all of your help! Please let me know if you need anything further.

Kind regards,

Dave

Product ingredient source information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
202-393-3903 PCT c/o, Lewis & Harrison 122 C St.NW, WDC 20001	71806-R
Active Ingredient(s) and/or representative test compound(s) 2-methyl-3(2H)-isothiazolone Kathon (Chem 107104)	Date 3/9/99
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor Non-food	Product Name PPM

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of all companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
E. David Lewis	3/9/99	E. David Lewis, Agent Plant Cell Technologies

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

STF ENV686F

Attachment to Certification with Respect to Citation of Data Form

Applicant: Plant Cell Technology, Inc.

Product Name: PPM

Date of Original Application: July 8, 1998

Date of Certification with Respect To Citation of Data Form: July 8, 1998

Active Ingredient: EPA Chemical No. 107103 (5-Chloro-2-methyl-3(2H)-isothiazolone), [redacted]

Companies Notified in Writing and Offered Compensation:

Rohm & Haas Company
100 Independence Mall West
Philadelphia, PA 19106

Chemical Manufacturers Association (Hasmukh Shah)
1300 Wilson Boulevard
Arlington, VA 22209

Companies Having Granted Permission to Cite Data

Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Active Ingredient: EPA Chemical No. 107104 (2-methyl-3(2H)-isothiazolone), [redacted]

Companies Notified in Writing and Offered Compensation:

Rohm & Haas Company
100 Independence Mall West
Philadelphia, PA 19106

Chemical Manufacturers Association (Hasmukh Shah)
1300 Wilson Boulevard
Arlington, VA 22209

Companies Having Granted Permission to Cite Data

Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Product ingredient source information may be entitled to confidential treatment

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date 3/9/99

EPA Reg No./File Symbol 71806-R

Applicant's/Registrant's Name & Address
Plant Cell Technologies
1920 N Street, N.W., Washington, DC 20036

Product
PPM

Ingredient 5-chloro-2-methyl-3-(2H)-isothiazolone and 2-methyl-3-(2H)-isothiazolone

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1	[redacted]		Plant Cell Tech (PCT)	OWN	
61-2(a) & (b)			PCT	OWN	
31-3			PCT	OWN	
62-1			PCT	OWN	
62-2			PCT	OWN	
62-3			LONZA	PER	
63-2			PCT	OWN	
63-3			PCT	OWN	
63-4			PCT	OWN	
63-5			PCT	OWN	
63-7			PCT	OWN	
63-8			PCT	OWN	
63-9			PCT	OWN	
63-10			PCT	OWN	
63-11			PCT	OWN	

Signature

Name and Title
E. David Lewis
Lewis & Harrison, Agent

Date
3/9/99

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved. OMB No. 2070-0060

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DATA MATRIX

Date 3/9/99

EPA Reg No./File Symbol 71806-R

Applicant's/Registrant's Name & Address Plant Cell Technologies
1920 N Street, N.W., Washington, DC 20036

Product
PPM

Ingredient 5-chloro-2-methyl-3-(2H)-isothiazolone and 2-methyl-3-(2H)-isothiazolone

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-4			Plant Cell Tech (PCT)	OWN	
81-5			PCT	OWN	
81-6			Rohm&Haas, Phila. PA	PAY	
81-6			CMA, Arlington, VA	PAY	

Signature

Name and Title
E. David Lewis
Lewis & Harrison, Agent

Date
3/9/99

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit o[illegible]aper version.

STF ENV688F

Public File Copy

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 9, 1999

EPA Reg No./File Symbol 71806-R

Applicant's/Registrant's Name & Address
Plant Cell Technologies, Inc.
1920 N Street, N.W.
Washinton, DC 20036

Product
PPM

Ingredient 5-chloro-2-methyl-3-(2H)-isothiazolone (Chem #107103) and 2-methyl-3-(2H)-isothiazolone (#107104)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1	IDENTITY OF INGREDIENTS		PCT	OWN	
61-2(A) & (B)	BEGINNING MATERIALS & MAN. PROCESS		PCT	OWN	
61-3	DISC. OF FORM OF IMPURITIES		PCT	OWN	
62-1	PRELIM. ANALYSIS		PCT	OWN	
62-2	CERT. OF LIMITS		PCT	OWN	
62-3	ANALYT. METHOD	43865202	LONZA, 17-17 RT208, FAIR LAWN NJ	PER	
63-2	COLOR		PCT	OWN	
63-3	PHYSICAL STATE		PCT	OWN	
63-4	ODOR		PCT	OWN	
63-5	MELTING POINT		PCT	OWN	
63-7	SPECIFIC GRAVITY		PCT	OWN	
63-8	SOLUBILITY		PCT	OWN	
63-9	VAPOR PRESSURE		PCT	OWN	
63-10	DISSOCIATION CONSTANT		PCT	OWN	
63-11	pH		PCT	OWN	

Signature

Name and Title
E. David Lewis, Lewis & Harrison
Agent, Plant Cell Technologies

Date
9 March 1999

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

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1920 N Street, N.W.
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Product
PPM

Ingredient 5-chloro-2-methyl-3-(2H)-isothiazolone (Chem #107103) and 2-methyl-3-(2H)-isothiazolone (#107104)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-13	STABILITY		PCT	OWN	
63-14	OXIDIZING/REDUCING ACTION		PCT	OWN	
63-15	FLAMMABILITY		PCT	OWN	
63-16	EXPLODABILITY		PCT	OWN	
63-17	STORAGE STABILITY		PCT	OWN	
63-18	VISCOSITY		PCT	OWN	
63-19	MISCIBILITY		PCT	OWN	
63-20	CORROSION CHARACTERISTICS		PCT	OWN	
63-21	DIELECTRIC BREAKDOWN		PCT	OWN	
81-1	ACUTE ORAL	CITE-ALL	Rohm&Haas, 100 Indep. Mall West, Phila. PA 19106	PAY	
81-1	ACUTE ORAL	CITE-ALL	CMA, 1300 Wilson Blvd., Arlington, VA 22209	PAY	
81-2	ACUTE DERMAL	CITE-ALL	Rohm&Haas 100 Indep. Mall West, Phila, PA 19106	PAY	
81-2	ACUTE DERMAL	CITE-ALL	CMA, 1300 Wilson Blvd., Arlington, VA 22209	PAY	
81-3	ACUTE INHALATION	CITE-ALL	Rohm&Haas, 100 Indep. Mall West, Phila, PA 19106	PAY	
81-3	ACUTE INHALATION	CITE-ALL	Rohm&Haas, 100 Indep. Mall West, Phila. PA 19106	PAY	

Signature

Name and Title
E. David Lewis, Lewis & Harrison
Agent, Plant Cell Technologies

Date
9 March 1999

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401 M Street, S.W.
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Product
PPM

Ingredient 5-chloro-2-methyl-3-(2H)-isothiazolone (Chem #107103) and 2-methyl-3-(2H)-isothiazolone (#107104)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-4	EYE IRRITATION		PCT	OWN	
81-51	DERMAL IRRITATION		PCT	OWN	
81-6	DERMAL SENSITIZATION	CITE-ALL	Rohm&Haas, 100 Indep. Mall West, Phila. PA 19106	PAY	
81-6	DERMAL SENSITIZATION	CITE-ALL	CMA, 1300 Wilson Blvd., Arlington, VA 22209	PAY	

Signature

Name and Title
E. David Lewis, Lewis & Harrison
Agent, Plant Cell Technologies

Date
9 March 1999

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
PCT c/o, Lewis & Harrison 122 C St.NW, WDC 20001 202-393-3903	71806-R
Active Ingredient(s) and/or representative test compound(s) Kathon 5-chloro-2-methyl-3(2H)-isothiazolone(Chem 107103)	Date 3/9/99
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor Non-food	Product Name PPM

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of all companies sent offers of compensation (the Data Matrix form should be used for this purpose).

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☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
E. David Lewis	3/9/99	E. David Lewis, Agent Plant Cell Technologies

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

STF ENV686F

Attachment to Certification with Respect to Citation of Data Form

Applicant:	Plant Cell Technology, Inc.
Product Name:	PPM
Date of Original Application:	July 8, 1998
Date of Certification with Respect To Citation of Data Form:	July 8, 1998

Active Ingredient: EPA Chemical No. 107103 (5-Chloro-2-methyl-3(2H)-isothiazolone), [redacted]

Companies Notified in Writing and Offered Compensation:

Rohm & Haas Company
100 Independence Mall West
Philadelphia, PA 19106

Chemical Manufacturers Association (Hasmukh Shah)
1300 Wilson Boulevard
Arlington, VA 22209

Companies Having Granted Permission to Cite Data

Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Active Ingredient: EPA Chemical No. 107104 (2-methyl-3(2H)-isothiazolone), [redacted]

Companies Notified in Writing and Offered Compensation:

Rohm & Haas Company
100 Independence Mall West
Philadelphia, PA 19106

Chemical Manufacturers Association (Hasmukh Shah)
1300 Wilson Boulevard
Arlington, VA 22209

Companies Having Granted Permission to Cite Data

Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Product ingredient source information may be entitled to confidential treatment

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

FAX COVER SHEET

DATE:	December 15, 1998	**TIME:**	6:37 PM
TO:	Karen Leavy-Munk	**PHONE**	703-308-6237
		FAX	703-308-6467
FROM:	E. David Lewis		
RE:	Plant Cell Technology, Inc. – PPM (EPA File Symbol 71806-R)		

Number of pages including cover sheet: 2

Message

Karen –

[redacted]

I would be happy to wait until after Anna Skapars returns next year to resolve her question on the alternate formula; but if you could issue the basic registration before the end of the year on the basis of the enclosed, we would certainly appreciate it.

Once again, thanks for all of your help! Please let me know if you need anything further.

Kind regards,

Dave

Product ingredient source information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

SUBMISSION BAR CODE # 5557842 REVIEWER K. Leavy-Munk

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 71806-R PM 33 ACTION CODE 185

DESCRIPTOR Scientific Data

[ ] CHILD RESISTANT PACKAGING: [ ] CERTIFICATION
[ ] NON-RESIDENTIAL USE ONLY
[ ] NOT APPLICABLE

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL

PROPOSED CLASSIFICATION: [ ] GENERAL [ ] RESTRICTED USE

DATE ON APPLICATION	EPA RECEIVE DATE	PM RECEIVE DATE
07 08 98	07 09 98	07 09 98

METHOD OF SUPPORT

[ ] CITE-ALL
[ ] SELECTIVE
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

FORMULATORS EXEMPTION

[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
TOXICOLOGY				
HED TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER _____				

STATUS _____

RESPONSE CODE 12 RESPONSE DATE 12/15/99

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 2 5 1999

Plant Cell Technology, Inc.
1920 North Street, NW
Washington, DC 20036

Attention: Dave Lewis, Agent

Subject: PPM
EPA File Symbol 71806-R
Submission Dated December 15, 1998

The application referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide act as amended is incomplete. Before the agency can continue processing your application, you must submit additional information as outlined below.

Product Chemistry

As indicated in our last letter (November 19, 1998) submit a revised alternate Confidential Statement of Formula (CSF) form and increase the amount of active ingredient source material so that the total of the two components would be the same as listed in the CSF for the basic formulation. The alternate formulation is not acceptable.

Product Toxicology

The submitted acute Eye Irritation and Skin Irritation studies were reviewed and found to be acceptable. Your references to specific registered products as "Me-Toos" is unacceptable (refer to the enclosed toxicology review). However, since you are using the Cite-All Method of Support for the remaining acute toxicology data requirements, and your product formulation is considered to be substantially similar to other registered pesticide products, no additional toxicology data is required at this time.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

Administrative Requirements

Submit an updated "Certification With Respect To Citation Of Data" form, an updated data matrix (including the copy to be filed with EPA's Public Docket), and the list of data submitters you are offering to compensate under the Cite-All option under the Selective Method of Support. You may call 703-305-6549 for the latest version of these forms.

Labeling

Submit five copies of draft labeling revised in accordance with the following comments:

a. Following your product name include a product descriptor statement (e.g., "Preservative for Plant Tissue Culture Media").

b. Change ". . . PPM is both biocidal and biostatic" to ". . . PPM is both biocidal and (>2 ml PPM/L of media) and biostatic (<2ml PPM/L of media) when diluted in plant growth media."

c. Provide more explicit use directions which indicates where and how your product is to be used, e.g.,: "PPM is an excellent preservative agent which can be used in research laboratories to inhibit the growth of, or kill bacteria and fungi in plant tissue culture growth media."

d. Indicate that "PPM (5 - 20ml) when diluted with plant growth media (5 - 20ml PPM/liter growth media) is effective as a microbiocide against non-human health pathogenic organisms."

e. Change ". . . explants should be mildly sterilized either with 1 - 5% EPA registered leach solution . . ." to read ". . . explants should be treated with an EPA registered plant disinfectant."

f. Change ". . . supplemented with 5 - 20 ml/L PPM" to read ". . . supplemented with 5 - 20 ml/L PPM/media mixture."

g. Add the following statement to your Precautionary Statement section: "Use rubber gloves when handling."

If you have any questions concerning this letter please contact Marshall Swindell at 703-308-6341.

Sincerely yours,

M Swindell

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510W)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Subject: D249022
PPM, Product No. 71806-R

From: Wallace Powell, Biologist
Efficacy and Science Support Branch
Antimicrobials Division (7510W)

Thru: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Efficacy and Science Support Branch
Antimicrobials Division (7510W)

Michele E. Wingfield, Chief
Efficacy and Science Support Branch
Antimicrobials Division (7510W)

To: Marshall Swindell, Product Manager, Team 33
Karen Leavy-Munk, Team Reviewer, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510W)

BACKGROUND. The applicant, Plant Cell Technology, Inc., has submitted primary eye irritation and primary dermal irritation data – MRID Nos. 445993-03 and 445993-04, respectively. The studies were submitted in support of product registration for the product PPM, EPA File Symbol 71806-R. The applicant additionally has used the 'cite-all' method of data support/compensation for the acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, and dermal sensitization data requirements.

Active Ingredients	% by weight	CAS No.
(107103) 5-chloro-2-methyl-3(2H)-isothiazolone	0.135	26172-55-4
(107104) 2-methyl-3(2H)-isothiazolone	0.0412	2682-20-4
Inert Ingredients	99.8238	

RECOMMENDATION

In choosing the cite-all option, the applicant references EPA Reg. Nos. [redacted] as similar products. The subject product, PPM, would appear similar in composition to Reg. No.

MAY CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Product ingredient source information may be entitled to confidential treatment

[redacted]

Acute toxicity categories do not appear to have been explicitly established in the registration file of either of the referenced products. However, if we examine the EPA-accepted label for Reg. No. [redacted] the precautionary statements on the label are reflective of the following categories:

[redacted]

§81-3 and §81-6, Acute Inhalation Toxicity and Dermal Sensitization: Toxicity categories for these two acute effects can be assigned to PPM based on the above categories for the referenced product. For the dermal sensitization effect, PPM can be 'assumed' to be a sensitizer, for the sake of requiring a label statement to alert users to the possibility of sensitization. As for acute inhalation toxicity, PPM can be assigned to Category III, or a waiver can be issued based on the product use pattern. (Note: Because it is possible that the actual hazard level for PPM is in the Category IV range, Category III might represent an overstatement of the hazard. However, this is considered allowable in the context of Category III versus IV, even though it is not generally allowable in the context of Category II versus III or I versus II.)

Because the proposed label has no inhalation hazard-related statement, and because the applicant claims that there is no inhalation exposure to the product, it is assumed that the applicant would prefer a waiver, rather than a Category III classification which would trigger the requirement of certain label statements. A waiver is recommended based on the product use pattern. No significant inhalation exposure is expected. The applicant states that "PPM is applied to plant cell tissue media by pump or pipette in minute quantities. It is never applied by spraying or misting and the vapor pressure of PPM is essentially that of water."

§81-1 and §81-2, Acute Oral Toxicity and Acute Dermal Toxicity: Acute oral and acute dermal toxicity categories cannot be assigned to PPM based on the referenced product. To assign Category II is to assume that the large difference in concentration, between the referenced product and PPM, has no significant effect on the hazard level. (Remember, the data requirement applies to the product 'as sold', not to the in-use dilution.) This effect could be major or minor. To assign Category II might be correct, or it might be a significant overstatement of the hazard. Category III might be correct, or it might be a significant understatement of the hazard. Neither category is acceptable without adequate supporting data or rationale.

§81-4, Primary Eye Irritation: Toxicity Category III (i.e., corneal involvement or 'positive' irritation, clearing in 7 days or less). The submitted study is acceptable.

§81-5, Primary Dermal Irritation: Toxicity Category III (moderate irritation). The submitted study is acceptable.

The acute toxicity regulatory profile for PPM is summarized in the table below.

Data Requirement	Means of Support	Status / Category
Acute Oral Toxicity	Product reference under 'cite-all' option	Unacceptable
Acute Dermal Toxicity	Product reference under 'cite-all' option	Unacceptable
Acute Inhalation Toxicity	Product reference under 'cite-all' option	Waived / IV*
Primary Eye Irritation	Submitted study, MRID 445993-03	Acceptable / III
Primary Dermal Irritation	Submitted study, MRID 445993-04	Acceptable / III
Dermal Sensitization	Product reference under 'cite-all' option	Sensitizing

* This Category IV is based on the product use pattern and is **not** meant to characterize the product formulation.

PRODUCT LABELING

Determination of the required precautionary and practical treatment label statements cannot be completed until the acute oral and acute dermal toxicity data requirements have been met.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4)

Reviewer: W. Powell
Product No.: 71806-R
DP Barcode: D249022
MRID No.: 445993-03
Report No.: 5812 (Study No.)
Report Date: 05/20/98
Author: Gary Wnorowski

Conclusion:
Toxicity Category: III (i.e., corneal involvement or 'positive' irritation, clearing in 7 days or less)
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Deficiencies: None noted

Testing Facility: Product Safety Labs; 725 Cranbury Road, East Brunswick, New Jersey 08816

Test Material: Plant Preservative Mixture, Lot #203, a clear, light yellow liquid

Test Animal:
Rabbit, New Zealand albino
Age: adult (not further specified)
Weight: not indicated
Source: Davidson's Mill Farm, South Brunswick, NJ

Test Method:

0.1 ml of the undiluted test material was instilled into the conjunctival sac of one eye of each of three rabbits per sex that were pre-screened for eye abnormalities. The eyelids were held together for about 1 second. The other eye was untreated and served as a control. No eye wash was administered. Ocular irritation was evaluated at 1, 24, 48, and 72 hours and 4 and 7 days after dosing, and graded according to the Draize criteria. Fluorescein dye was used beginning at 24 hours after dosing; where corneal staining occurred, the solution was re-applied at subsequent observations to evaluate corneal damage or verify reversal of effects.

Results and Discussion:

The numbers of animals showing 'positive' irritation response (as defined by EPA guidelines) at each observation time are indicated in the following table.

Table: Eye Irritation Responses

Areas observed	Number of 'positive'* irritation scores (Draize criteria) per number of animals tested					
	1 Hour	24 Hrs	48 Hrs	72 Hrs	4 Days	7 Days
Cornea: Opacity	0/6	4/6	3/6	3/6	0/6	0/6
Iris	0/6	1/6	1/6	1/6	0/6	0/6
Conjunctivae: Redness	6/6	6/6	5/6	2/6	0/6	0/6
Chemosis	2/6	2/6	2/6	2/6	0/6	0/6

*'Positive' as defined by EPA guidelines

Severity of corneal opacity and iridal involvement were limited to grade 1 on the Draize scale, and disappeared by day 4. Conjunctival redness was severe (grade 3) at 1 hour in 6/6 animals, while chemosis reached grade 2 in 2/6 animals at hours 1 though 72. Redness and chemosis completely disappeared by day 7, and any 'positive' degree of signs of these effects disappeared by day 4. The data indicate Category III for primary eye irritation (i.e., corneal involvement or 'positive' irritation, clearing in 7 days or less).

All animals appeared active and healthy. Clinical signs: none, except those of eye irritation.

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (§81-5)

Reviewer: W. Powell
Product No.: 71806-R
DP Barcode: D249022
MRID No.: 445993-04
Report No.: 5813 (Study No.)
Report Date: 05/20/98
Author: Gary Wnorowski

Conclusion:
Toxicity Category: III (moderate irritation)
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations: None noted

Testing Facility: Product Safety Labs; 725 Cranbury Road, East Brunswick, New Jersey 08816

Test Material: Plant Preservative Mixture, Lot #203, a clear, light yellow liquid

Test Animal:
Rabbit, New Zealand albino
Age: adult (not further specified)
Weight: not indicated
Source: Davidson's Mill Farm, South Brunswick, NJ

Test Method:

0.5 gram of the test substance was applied undiluted to the dorsal and/or trunk area of each of 3 rabbits per sex, on a 6 cm^2 clipped area. This site was then covered with gauze and wrapped with semi-occlusive tape. Elizabethan collars were placed on each animal. After a 4 hour exposure period, the dressings were removed and the test sites gently wiped with water and clean towel. The test sites were then observed for dermal effects at approximately 1, 24, 48, and 72 hours and 7 and 10 days after removal of the dressings. Severity of erythema and edema was scored using the Draize criteria.

Results and Discussion:

Observed erythema severity was at its highest at 24 hours, at which time it was observed to be moderate to severe in 4/6 animals. Observed edema peaked at 1 hour, being severe in 2/6 animals. By 72 hours, overall erythema and edema response was very slight. All signs disappeared by day 10 except for desquamation present in 3/6 animals. Observation was halted after Day 10. These observations indicate moderate irritation and Toxicity Category III for primary dermal irritation.

All animals appeared active and healthy. Clinical signs: none, except those of dermal irritation.

DP BARCODE: D249022

CASE: 062494 DATA PACKAGE RECORD DATE: 09/01/98
SUBMISSION: S548005 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 184 AmD-OC-NEW NON F/F USE
CHEMICALS: 107103 5-Chloro-2-methyl-3(2H)-isothiazolone 0.1350%
107104 2-Methyl-3(2H)-isothiazolone 0.0412%

ID#: 071806-R PPM
COMPANY: 071806 PLANT CELL TECHNOLOGY, INC.
PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B
PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-308-6237 ROOM: CS1 6W9
RECEIVED DATE: 07/09/98 DUE OUT DATE: 03/06/99

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 249022 EXPEDITE: N DATE SENT: 09/01/98 DATE RET.: / /
CHEMICAL: 107103 5-Chloro-2-methyl-3(2H)-isothiazolone
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : AD	07/09/98	/ /
BRAN: EASSB	09/01/98	/ /
SECT: CTT	9/1/98	/ /
REVR : WPowell	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 02/18/99
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

The company has submitted the eye and skin irritation studies on this product and is going cite-all on the thers(i.e., Inhalation, Dermal, oral, and Skin Sensitization).
The company has also submitted a justification page in the file of why the tox. data he is offering to pay for can be used in support of his product (include it and the MSDS sheets with the tox. data package). The submitted tox. studies are as follows: Primary Eye Irritation(44599303) and Primary Skin Irritation (44599304).

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

PPM is a broad-spectrum preservative and biocide. It targets fundamental enzymes in the Krebs cycle and in the Electron Transport Chain. Depending on the dose level, *PPM* is both biocidal (>2ml/L) and biostatic (<2ml/L).

1. Media containing *PPM* may be dispensed outside the laminar flow hood (LFH) exposed to the ambient air. The plates should be covered soon after agar solidification. In the event a pump dispenses the media, we recommend passing autoclaved hot water through the hoses before and after dispensing media.

2. Heat sensitive or heat stable liquid media containing *PPM* do not need to be sterilized by Millipore filters or autoclaved provided that it will be stored in sterile containers and that the stock solutions are not previously contaminated. In rich media containing 200 mg/liter or more of amino acids or proteins, it is recommended to filter the media with the *PPM*.

PPM

ACTIVE INGREDIENTS:

5-Chloro-2-methyl-3(2H)-isothiazolone.....	0.135%
2-methyl-3(2H)-isothiazolone.....	0.0412%
INERT INGRDIENTS.....	99.8238%

KEEP OUT OF REACH OF CHILDREN
CAUTION
EPA REG. NO. **EPA EST NO.**

3. Working in the LFH the utensils (forceps or scalpels) do not need to be flamed. They may be periodically dipped in 70% alcohol. The LFH does not need to be certified and the work can also be done outside the LFH on a clean surface for a period not exceeding 2 - 3 hours.

4. *PPM* comes in an acidic liquid solution (pH 3.8) and should be stored at 4°C. The recommended dose is 0.5 - 2.0 ml of *PPM* per liter of medium. Higher doses are required to treat endogenous contamination or to obtain Agrobacteria free plant material.

5. *PPM* is less effective when exposed to high density of bacteria or fungi spores found regularly on a seed's coat. For *in vitro* germination, seeds should be conventionally surface sterilized with EPA registered bleach. Therefore, in the presence of *PPM* (in the germination medium), the seeds can be rinsed under tap water in a non-sterile strainer and left to dry preferably in the LFH. Protoplast isolation solution should be sterilized mechanically through Millipore filters with the *PPM*. If the utensil ends have touched active bacteria, fungi culture or otherwise suspected of being contaminated, they should be sterilized by autoclave or by use of an electric heating element.

6. *Endogenous Contamination:*

Plant tissue culture media containing *PPM* at doses of 5-20 ml/l can be used to eliminate endogenous contamination in seeds and plant-explants. In such cases, the seeds or the explants should be mildly surface st[illegible]ed, eit[illegible] with 1-5% EPA registered bleach solution plus a few drops of Tween 20, or for 30-60 seconds quick-dip in 70% alcohol, or in a 3% hydrogen peroxide solution. After rinsing with DD water, explants or buds should be embedded or placed in autoclaved semisolid or liquid medium respectively. The proper media such as callus proliferation or regeneration can be used with only ¼ strength of the inorganic salts, supplemented with 5-20 ml/l *PPM*. After 2-5 days the explants can be transferred without rinsing into a similar media (full strength inorganic salts) supplemented with at least 0.5 ml/l *PPM* at 20-24 degrees centigrade. Seeds can be transferred to germination medium (full strength of inorganic salts) supplemented with 0.5 ml/l *PPM* after 5-10 days.

It is up to the researchers to determine the optimal combination of *PPM* doses and time exposure. Different plant types and different explant sources are highly varied in their response to *PPM*.

Storage and Disposal

Storage: Ideal storage temperature is 39°F (4° C). Do not store at temperatures in excess of 70°F (21°C).

Pesticide Disposal: Do not contaminate water, food, or feed by storage and disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility

Container Disposal: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

NET CONTENTS:

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

Pages 48-56 Product ingredient source information may be entitled to confidential treatment

Record Number 5548005

Reference Number _____

Input Date _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 71806-R PM 33 |8| Action Code 184

|10| Descriptor (Amend/Resubmissions only) _____

|5| Intrastate Call-In ☐ (Y) Yes ☐ (N) No

|__| Child-Resistant Packaging

☐ (C) Certification

☐ (S) Service Person

☐ (R) Non-Residential Use Only

☐ (N) Not-Applicable

|20| Registration Type:

☐ (1) Conditional ☐ (2) Unconditional

|25| Proposed Classification:

☐ (R) Restricted

☐ (G) General

|30| Final Classification

☐ (R) Restricted

☐ (N) Not Classified

|35| Date on Application: 07 / 08 / 98 (MO / DAY / YR)

|04| EPA Received Dated: 07 / 09 / 98 (MO / DAY / YR)

|40| Date Received by PM: 07 / 09 / 98 (MO / DAY / YR)

|80| Method of Support:

☐ (1) Cite-All

☐ (2) Not Applicable

☐ (3) Not Submitted

☐ (6) Owner Submission

☐ (7) Total Submission

☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
RD					
PM					
PL					
CH					
EF					

|108| Status: _____

|115| FINAL ACTION Response Code 11

|120| Response Date 11 / 19 / 98

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 19 1998

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Plant Cell Technology, Inc.
1920 North Street, NW
Washington, DC 20036

Attention: E. David Lewis

Subject: PPM
EPA File Symbol Number 71806-R
Your Submission Dated July 8, 1998
EPA Received Date September 9, 1998

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is unacceptable for the following reasons:

1. The provided product chemistry data in MRID Nos. 445993-01 and 445993-02 provides data for Guideline Series 61, 62, and 63. These data are in compliance with 40 CFR part 158.155 through 158.190. It satisfies product chemistry data for this product, except for series 62-3, Analytical Method, to verify for the certified limits.

2. Provide the Analytical Methods for the active ingredient.

3. Resubmit the revised alternate Confidential Statement of Formula and slightly increase the active ingredient source so that the total of the two components would be the same for the basic and the alternate Confidential Statement of Formula. Please note that the alternate Confidential Statement of Formula is lower.

However the basic Confidential Statement of Formula dated July 8, 1998 is in compliance with PR Notice 91-2. It agrees with the label. The basic Confidential Statement of Formula is acceptable.

If you have any questions on concerns, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely yours,

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7510W)

FQPA

DP BARCODE: D249023

CASE: 062494 DATA PACKAGE RECORD DATE: 09/01/98
SUBMISSION: S548005 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 184 AmD-OC-NEW NON F/F USE
CHEMICALS: 107103 5-Chloro-2-methyl-3(2H)-isothiazolone 0.1350%
107104 2-Methyl-3(2H)-isothiazolone 0.0412%

ID#: 071806-R PPM
COMPANY: 071806 PLANT CELL TECHNOLOGY, INC.
PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B
PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-308-6237 ROOM: CS1 6W9
RECEIVED DATE: 07/09/98 DUE OUT DATE: 03/06/99

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 249023 EXPEDITE: N DATE SENT: 09/01/98 DATE RET.: / /
CHEMICAL: 107103 5-Chloro-2-methyl-3(2H)-isothiazolone
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : AD	07/09/98	/ /
BRAN: EASSB	09/01/98	/ /
SECT: CTT	9/1/98	/ /
REVR : Anna	/ /	/ /
CONTR: Anna Skapar 11-9-98	/ /	/ /

ADMIN DUE DATE: 02/18/99
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the submitted Chemistry data under MRID #s
445993-01 amd 445993-02.
A copy of the CSF and product labeling are enclosed

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
249022	EASSB/CTT	09/01/98	02/18/99	Y	Y	Y

Marshall,
This is not an antimicrobial product. Should probably go to RS. Mueller

PRODUCT CHEMISTRY REVIEW

END-USE PRODUCT [✓] MANUFACTURING-USE PRODUCT [ ]
EPA Reg. No. (or File Symbol No.) 71806-R

Registration [✓] **Reregistration [ ]**
Case No.: _____

DP Barcode/Chemist: D249023 Anna Skapars

1) 3)

2) 4)

1. Product Name: PPM
2. Company: Plant Cell Technology, Inc.
3. Type of Submission: New [✓] Resubmission [ ] Amendment [ ]
   "ME-TOO" [ ] Alternate Formulation [ ] REPACK [ ]
   Expt Use Permit [ ] Other (Specify) _____

---

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [✓]
  - Are all TGAIs used registered • yes [✓] • no [ ]
- Integrated formulation system [ ]
- If "ME-TOO", specify EPA Reg. No. of existing product:

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40CFR§180.1001:
• yes [ ] • no [ ]. If yes: • c[ ] • d[ ] • e [ ]
Cleared for non-food use: • yes [✓] • no [ ]

4c. Physical state of product: Liquid

4d. The chemical IDs, analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in GRN 61, 62, and 63-7, 63-12, and 63-15, respectively. • yes [✓] • no [ ]

4e. Density (or bulk density for solids): at °C. 8.528 lbs/gal

4f. pH (if dissolved or dispersed in water): 3.91 at 25°C

4g. Flash point and/or flame extension: N/A

4h. NCs and CLs are acceptable: • [✓] • not acceptable [ ]

4i. Active ingredient(s)

	NC-	LCL	UCL
A. 5-Chloro-2-methyl-3(2H)-isothiazolone	0.135		
B. 2-Methyl-3(2H)-isothiazolone	0.0412		
C.			
D.			

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have an UCL: • yes [ ] • no [ ] • not applicable [✓]
- All impurities ≥ 0.1% in the product have been identified: • yes [ ] • no [ ] • not applicable [✓]

---

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: • yes [✓] • no [ ]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: • yes [ ] • no [✓]
- 1% or more of methyl alcohol: • yes [ ] • no [✓]
- sodium nitrite at any level: • yes [ ] • no [✓]
- a toxic List 1 inert at any level: • yes [ ] • no [✓]
- arsenic in any form: • yes [ ] • no [✓]

5c. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?
• yes [ ] • no [ ] • not applicable [✓]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label:
• yes [✓] • no [ ] • not applicable [ ]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses: • yes [✓] • no [ ]

6f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information):
• yes [ ] • no [✓]

6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

6a. Chemical IDs/Manufacture/Analytical Information	Accept of Information	MRID No.
61-1 Chemical ID (see Appendix)[1]	A	CSF.
61-2a Manufacturing Process[2]	A	CSF
61-2b Formulation Method[3]	A	CSF
61-3 Discussion of Impurities[4]	A	445993-02
62-1 Analysis[5]	N/A	
62-2 Certified Limits[6]	A	CSF
62-3 Analytical Method for AIs[7]		

SUBJECT: **PRODUCT CHEMISTRY REVIEW – Antimicrobials Division**
DP Barcode D249023 **Reg. No. or File Symbol** 71806-R
Manufacturing-Use [ ] **OR End-Use Product** [✓]

TO: Marshall Swindell/ Karen Leavy-Munk
PM Team No. 33

FROM: Anna Skapars, Chemist
Efficacy and Science Support Branch

THRU: Michelle Wingfield, Acting Chief
Efficacy and Science Support Branch

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

This application is for registration of a new product broad-spectrum preservative and biocide.

A. Provided product chemistry data in MRID No's 445993-01 and 445993-02 provides data for Guideline Series 61, 62 and 63. These data are in compliance with 40 CFR part 158.155 through 158.190 and it satisfies product chemistry data for this product, except for Series 62-3 Analytical Method to verify certified limits.

B. Registrant should provide Analytical method for the active ingredient.

C. Basic Confidential Statement of Formula dated 7-8-98 is in compliance with PR Notice 91-2, it agrees with the label and basic CSF is acceptable.

Registrant should resubmit revised alternate Confidential Statement of Formula and increase slightly active ingredient source so that the total of two components would be the same for the basic and the alternate.
Note that the alternate is somewhat lower.

Anna Skapars
11-9-98

Pages 65-66 Confidential Statement of Formula may be entitled to confidential treatment

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

PPM is a broad-spectrum preservative and biocide. It targets fundamental enzymes in the Krebs cycle and in the Electron Transport Chain. Depending on the dose level, *PPM* is both biocidal (>2ml/L) and biostatic (<2ml/L).

1. Media containing *PPM* may be dispensed outside the laminar flow hood (LFH) exposed to the ambient air. The plates should be covered soon after agar solidification. In the event a pump dispenses the media, we recommend passing autoclaved hot water through the hoses before and after dispensing media.

2. Heat sensitive or heat stable liquid media containing *PPM* do not need to be sterilized by Millipore filters or autoclaved provided that it will be stored in sterile containers and that the stock solutions are not previously contaminated. In rich media containing 200 mg/liter or more of amino acids or proteins, it is recommended to filter the media with the *PPM*.

PPM

ACTIVE INGREDIENTS:

5-Chloro-2-methyl-3(2H)-isothiazolone.....	0.135%
2-methyl-3(2H)-isothiazolone.....	0.0412%
INERT INGRDIENTS.....	99.8238%

KEEP OUT OF REACH OF CHILDREN
CAUTION
EPA REG. NO. **EPA EST NO.**

3. Working in the LFH the utensils (forceps or scalpels) do not need to be flamed. They may be periodically dipped in 70% alcohol. The LFH does not need to be certified and the work can also be done outside the LFH on a clean surface for a period not exceeding 2 - 3 hours.

4. *PPM* comes in an acidic liquid solution (pH 3.8) and should be stored at 4°C. The recommended dose is 0.5 - 2.0 ml of *PPM* per liter of medium. Higher doses are required to treat endogenous contamination or to obtain Agrobacteria free plant material.

5. *PPM* is less effective when exposed to high density of bacteria or fungi spores found regularly on a seed's coat. For *in vitro* germination, seeds should be conventionally surface sterilized with EPA registered bleach. Therefore, in the presence of *PPM* (in the germination medium), the seeds can be rinsed under tap water in a non-sterile strainer and left to dry preferably in the LFH. Protoplast isolation solution should be sterilized mechanically through Millipore filters with the *PPM*. If the utensil ends have touched active bacteria, fungi culture or otherwise suspected of being contaminated, they should be sterilized by autoclave or by use of an electric heating element.

6. *Endogenous Contamination:*

Plant tissue culture media containing *PPM* at doses of 5-20 ml/l can be used to eliminate endogenous contamination in seeds and plant-explants. In such cases, the seeds or the explants should be mildly surface sterilized, either with 1-5% EPA registered bleach solution plus a few drops of Tween 20, or for 30-60 seconds quick-dip in 70% alcohol, or in a 3% hydrogen peroxide solution. After rinsing with DD water, explants or buds should be embedded or placed in autoclaved semisolid or liquid medium respectively. The proper media such as callus proliferation or regeneration can be used with only ¼ strength of the inorganic salts, supplemented with 5-20 ml/l *PPM*. After 2-5 days the explants can be transferred without rinsing into a similar media (full strength inorganic salts) supplemented with at least 0.5 ml/l *PPM* at 20-24 degrees centigrade. Seeds can be transferred to germination medium (full strength of inorganic salts) supplemented with 0.5 ml/l *PPM* after 5-10 days.

It is up to the researchers to determine the optimal combination of *PPM* doses and time exposure. Different plant types and different explant sources are highly varied in their response to *PPM*.

Storage and Disposal

Storage: Ideal storage temperature is 39°F (4° C). Do not store at temperatures in excess of 70°F (21°C).

Pesticide Disposal: Do not contaminate water, food, or feed by storage and disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility

Container Disposal: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

NET CONTENTS:

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

JUL 21 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/09/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

445993-00

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

July 9, 1999

Hand Delivered

Office of Pesticide Programs
Antimicrobial Division (7510W)
Document Processing Desk (APPL)
Room 258, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Attn: Marshall Swindell, Product Manager 33

Dear Mr. Swindell:

RE: Plant Cell Technology, Inc., Application to Register PPM (EPA Reg. No. ~~– Not Yet Assigned~~) 71806-R

As Agent for Plant Cell Technology, Inc., 1920 N Street NW, Washington, DC 20036-1, we are applying for registration of the above referenced end-use product. In support of this application we are submitting the following:

1) Application for Pesticide Registration (OPP Identifier Number 265351);

2) One copy of the basic and alternate Confidential Statements of Formula (EPA Form 8570-4);

3) Five copies of proposed draft labeling;

4) Formulator's Exemption Statement;

5) Certification with respect to citation of data (selective method of support) with attached matrix and applicable waiver requests; and,

6) Letter of authorization.

Also enclosed are three copies each of the following data:

"Physical and Chemical Characteristics of PPM: pH, Viscosity, and Relative Density," D. Sinning, 7 pages, Guideline Reference Nos. 830.7000, 830.7100, and 830.7300.

MRID No. 44599301

"Product Chemistry Data in Support of Registration of PPM;" Plant Cell Technology, Inc., 9 pages plus a confidential attachment, Guideline Reference Series 61, 62, and 63.

MRID No. 44599302

"Primary Eye Irritation," G. Wnorowski, 21 pages, Guideline Reference No. 81-4

MRID No. 44599303

"Primary Skin Irritation," G. Wnorowski, 16 pages, Guideline Reference No. 81-5

MRID No. 44599304

Lewis & Harrison is acting as the company contact and official of record for all regulatory matters associated with this application. Accordingly, I would appreciate your sending all correspondence including the Report of Analysis for Compliance with PR Notice 86-5 and the DER's to my attention.

Sincerely,

E. David Lewis
for,
Plant Cell Technology, Inc.

EDL/d

Enclosures

445993-00

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
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EDL/d

Enclosures

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NET CONTENTS:

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

NF/FT

(B

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
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July 9, 1998 Hand Delivered

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Antimicrobial Division (7510W)
Document Processing Desk (APPL)
Room 258, Crystal Mall 2
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Arlington, Virginia 22202

Attn: Marshall Swindell, Product Manager 33

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4) Formulator's Exemption Statement;

5) Certification with respect to citation of data (selective method of support) with attached matrix and applicable waiver requests; and,

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*MRID No.*_____

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*MRID No.*_____

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Sincerely,

E. David Lewis
for,
Plant Cell Technology, Inc.

EDL/d

Enclosures

PLANT CELL TECHNOLOGY, INC.

1920 "N" Street, NW
Ste. 750
Washington, D.C. 20036
Telephone: (202) 463-0904
Fax: (202) 822-6410

May 12, 1998

Mr. Steven Johnson
Director, Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall, Building 2
Arlington, VA 22202

Dear Mr. Johnson:

This letter authorizes Lewis & Harrison, LLC of 122 C Street, N.W., Suite 740, Washington, DC 20001, to act as agent on behalf of Plant Cell Technology, Inc. on all matters which may come before the U.S. Environmental Protection Agency.

Sincerely,

G. Roderick Gillette
C.O.O.

The foregoing was subscribed before me by G. Roderick Gillette on this 13th day of ~~March~~ May, 1998.

NOTARY PUBLIC
My Commission Expires _____

My Commission Expires June 14, 2001

N/FT

B

Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

EPA	United States Environmental Protection Agency Washington, DC 20460	☒ Registration ☐ Amendment ☐ Other	OPP Identifier Number 265351

Application for Pesticide - Section 1

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
~~Not Yet Assigned~~ 71806-R	Marshall Swindell	☒ None ☐ Restricted
4. Company/Product (Name) PPM	PM# 33	

5. Name and Address of Applicant *(Include ZIP Code)*
Plant Cell Technology, Inc.
1920 N Street, N.W.
Washington, DC 20036

☐ *Check if this is a new addresss*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) is necessary. (For Section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specifiy)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	250 milliliters to 4 liters	☒ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☒ Lithograph ☒ Paper glued ☒ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
E. David Lewis, Lewis & Harrison, 122 C St., NW, Washington, DC 20001	Agent	(202) 393-3903

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
E. David Lewis	Agent	(Stamped)
4. Typed Name E. David Lewis	5. Date July 8, 1998	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White- EPA File Copy (original) Yellow- Applicant Copy

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number
265351

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
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☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

aterial This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingllly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Specify the net contents of all retail containers for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number: 265351

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71806-R		☐ None ☐ Restricted
4. Company/Product (Name)	PM#	

5. Name and Address of Applicant *(Include ZIP Code)*

☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

aterial This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
ertification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingllly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

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3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
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1-5. Self-explanatory.
6. EPA Use Only.

Form approved. OMB NO. 2070-0060. Approval Expires 5-31-98

United States Environmental Protection Agency
Washington, D.C. 20460

EPA

Formulator's Exemption Statement

(40 CFR 152.85)

Applicants Name and Address	EPA File Symbol/Registration Number
Plant Cell Technology, Inc. 1920 N Street, NW Washington, DC 20036	~~Not yet assigned~~ 71806-R
	Product Name PPM
	Date of Confidential Statement of Formula (EPA Form 8570-4) July 8, 1998

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

5-chloro-2-methyl-3(2H)-isothialone
2-methyl-3(2H)-isothiazolone

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

	Source	
Active Ingredient	Product Name	Registration Number
5-chloro-2-methyl-3(2H)-isothialone and 2-methyl-3(2H)-isothiazolone	[redacted]	[redacted]

Product ingredient source information may be entitled to confidential treatment

Signature	Name and Title	Date
	E. David Lewis, Agent for Plant Cell Technology, Inc.	July 8, 1998

EPA Form 8570-27 (Rev. 7-91) White - EPA copy Yellow - Applicant copy

EPA	United States **Environmental Protection Agency** Washington, DC 20460	For Approved OMB No. 2070-0060 Approval Expires -02-28-95

Certification with Respect to Citation of Data

Applicants Name and Address	EPA File Symbol/Registration Number
Plant Cell Technology, Inc. 1920 N Street, NW Washington, DC 20036	~~Not yet assigned~~ 71806-R
	Product Name PPM
	Date of Application 7/8/98

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and this is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

[ ] I am the original submitter*; or

[ ] I have obtained the written permission of the original submitter for _____ (insert name of chemical), which is _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

a. [x] I am the original data submitter*; or

[x] I have obtained the written permission of the original data submitter for see attached (insert name of chemical), which is see attached (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*; or

b. [x] I have notified in writing the companies see attached (insert name of companies) for see attached (insert name of chemical) that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies see attached (insert names of companies) for see attached (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

Companies _____ (insert names of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted studies which I have cited (Selective method*).

4. [ ] I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature	Name and Title	Date
E. David Lewis	E. David Lewis, Lewis & Harrison, Agent for Plant Cell Technology, Inc.	7/9/98

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature	Name and Title	Date
E. David Lewis	E. David Lewis, Lewis & Harrison, Agent for Plant Cell Technology, Inc.	7/9/98

Attachment to Certification with Respect to Citation of Data Form

Applicant: Plant Cell Technology, Inc.

Product Name: PPM

Date of Original Application: July 8, 1998

Date of Certification with Respect To Citation of Data Form: July 8, 1998

Active Ingredient: EPA Chemical No. 107103 (5-Chloro-2-methyl-3(2H)-isothiazolone), [redacted]

Companies Notified in Writing and Offered Compensation:

Rohm & Haas Company
100 Independence Mall West
Philadelphia, PA 19106

Chemical Manufacturers Association (Hasmukh Shah)
1300 Wilson Boulevard
Arlington, VA 22209

Companies Having Granted Permission to Cite Data

Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Active Ingredient: EPA Chemical No. 107104 (2-methyl-3(2H)-isothiazolone), [redacted]

Companies Notified in Writing and Offered Compensation:

Rohm & Haas Company
100 Independence Mall West
Philadelphia, PA 19106

Chemical Manufacturers Association (Hasmukh Shah)
1300 Wilson Boulevard
Arlington, VA 22209

Companies Having Granted Permission to Cite Data

Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Product ingredient source information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

07/10/98

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Plant Cell Technology, Inc.
1920 N Street, N.W.
Washington, DC 20036

PRODUCT NAME: PPM
COMPANY NAME: Plant Cell Technology, Inc.
OPP IDENTIFICATION NUMBER: 265351
EPA FILE SYMBOL: 71806-R
EPA RECEIPT DATE: 07/08/98

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The office of Pesticides Programs has received your application for a new registration and it passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact Marshall Swindell, Product Manager 33 at (703)-308-6341.

Sincerely,

Front End Processing Staff
Information Resources & Services Division
Information Services Branch

1. Product Name: **PPM**	2. EPA Reg. No/File Symbol: ~~Not yet assigned~~ 71806-R	3. Formulator's Exemption Selected: YES **X** NO	4. Page 1 of 3
5. Applicant's (Company Name and Address: **Plant Cell Technology, Inc.** **1920 N Street, NW** **Washington, DC 20036**	6. Application for Registration Dated: July 8, 1998	7. Name of Active Ingredient(s): **5-Chloro-2-methyl-3(2H)-isothiazolone** **2-methyl-3-(2H)-isothiazolone**	
8. 40 CFR Part 158	9. Source of Data Satisfying Requirements		

8.a Guide-line Refer-ence Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (give name)	9d. Certificate of Per-mission (P) or Offer to Pay (OTP) or Offer to Jointly Develop Data (OJDD) enclosed: Indicate "P" or "OTP" or "OJDD"	9e. Public Litera-ture	9f. N.A. or Waiver or other (explain)	10. MRID Number, EPA Accession Number, or other identifying number
Section 158.190	Product Chemistry							
61-1	Identity of Ingredients	X	7/8/98					
61-2 (a) (b)	Beginning Materials & Manufacturing Process	X	7/8/98					
61-3	Discussion of Formation of Impurities	X	7/8/98					
62-1	Preliminary Analysis	X	7/8/98					
62-2	Certification of Limits	X	7/8/98					
62-3	Analytical method for enforcement of limits		11/29/95	Lonza, Inc.	P			43865202
63-2	Color	X	7/8/98					
63-3	Physical State	X	7/8/98					
63-4	Odor	X	7/8/98					
63-5	Melting Point	X	7/8/98					
63-7	Specific Gravity Density	X	7/8/98					

1. Product Name: **PPM**	2. EPA Reg. No/File Symbol: ~~Not yet assigned~~ 71806-R	3. Formulator's Exemption Selected: YES **X** NO	4. Page 2 of 3
5. Applicant's (Company Name and Address: **Plant Cell Technology, Inc.** **1920 N Street, NW** **Washington, DC 20036**	6. Application for Registration Dated: July 8, 1998	7. Name of Active Ingredient(s): **5-Chloro-2-methyl-3(2H)-isothiazolone** **2-methyl-3-(2H)-isothiazolone**	
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63-8	Solubility	X	7/8/98					
63-9	Vapor Pressure	X	7/8/98					
63-10	Dissociation Constant	X	7/8/98					
63-11	pH	X	7/8/98					
63-13	Stability	X	7/8/98					
63-14	Oxidizing or Reducing Action	X	7/8/98					
63-15	Flammability	X	7/8/98					
63-16	Explodability	X	7/8/98					
63-17	Storage Stability	X	7/8/98					
63-18	Viscosity	X	7/8/98					
63-19	Miscibility	X	7/8/98					
63-20	Corrosion Characteristics	X	7/8/98					
63-21	Dielectric Breakdown	X	7/8/98					

1. Product Name: **PPM**	2. EPA Reg. No/File Symbol: ~~Not yet assigned~~ 71806-R	3. Formulator's Exemption Selected: YES **X** NO	4. Page 3 of 3
5. Applicant's (Company Name and Address: **Plant Cell Technology, Inc. 1920 N Street, NW Washington, DC 20036**	6. Application for Registration Dated: July 8, 1998	7. *Name of Active Ingredient(s):* **5-Chloro-2-methyl-3(2H)-isothiazolone 2-methyl-3-(2H)-isothiazolone**	
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Section 158.340 81-1	Toxicology Acute Oral, Toxicity, rat			Selective Method – Cite-all Option (SMCAO)		See Attached		
81-2	Acute Dermal Toxicity, rabbit			SMCAO		See Attached		
81-3	Acute Inhalation Toxicity rat			SMCAO		See Attached		
81-4	Primary Eye Irritation, rabbit	X	7/8/98					
81-5	Primary Dermal Irritation	X	7/8/98					
81-6	Dermal Sensitization			SMCAO		See Attached		

LONZA

LONZA Inc.
Corporate Headquarters
17-17 Route 208
Fair Lawn, NJ 07410-2821

May 21, 1998

Mr. Marshall Swindell (PM-31)
Antimicrobial Division
Office of Pesticide Programs (7510W)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: **Authorization to access data in support of PPM**

Dear Mr. Swindell:

Lonza, Inc. authorizes Plant Cell Technologies, Inc., 1920 N Street, NW, Suite 750, Washington, D.C. 20036 to rely on the data listed below in support of its application to register the pesticide product "PPM":

Method of Analysis, contained in *"Isocil®, Preliminary Analysis and Certified Limits"*
MRID No. 43865202.

Although Plant Cell Technologies, Inc. is authorized to rely on this data, the data remain the property of Lonza, Inc. and access shall not be granted to anyone other than the employees of the EPA without the express written authorization of Lonza, Inc.

If you have any questions, you can contact me at 1-800-777-1875, ext. 2466.

Thank you.

Sincerely,

Ruth Trager

Ruth Trager
Manager Regulatory Services

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

PPM is a broad-spectrum preservative and biocide. It targets fundamental enzymes in the Krebs cycle and in the Electron Transport Chain. Depending on the dose level, *PPM* is both biocidal (>2ml/L) and biostatic (<2ml/L).

1. Media containing *PPM* may be dispensed outside the laminar flow hood (LFH) exposed to the ambient air. The plates should be covered soon after agar solidification. In the event a pump dispenses the media, we recommend passing autoclaved hot water through the hoses before and after dispensing media.

2. Heat sensitive or heat stable liquid media containing *PPM* do not need to be sterilized by Millipore filters or autoclaved provided that it will be stored in sterile containers and that the stock solutions are not previously contaminated. In rich media containing 200 mg/liter or more of amino acids or proteins, it is recommended to filter the media with the *PPM*.

PPM

ACTIVE INGREDIENTS:

5-Chloro-2-methyl-3(2H)-isothiazolone.....	0.135%
2-methyl-3(2H)-isothiazolone.....	0.0412%
INERT INGRDIENTS.....	99.8238%

KEEP OUT OF REACH OF CHILDREN
CAUTION
EPA REG. NO. **EPA EST NO.**

3. Working in the LFH the utensils (forceps or scalpels) do not need to be flamed. They may be periodically dipped in 70% alcohol. The LFH does not need to be certified and the work can also be done outside the LFH on a clean surface for a period not exceeding 2 - 3 hours.

4. *PPM* comes in an acidic liquid solution (pH 3.8) and should be stored at 4°C. The recommended dose is 0.5 - 2.0 ml of *PPM* per liter of medium. Higher doses are required to treat endogenous contamination or to obtain Agrobacteria free plant material.

5. *PPM* is less effective when exposed to high density of bacteria or fungi spores found regularly on a seed's coat. For *in vitro* germination, seeds should be conventionally surface sterilized with EPA registered bleach. Therefore, in the presence of *PPM* (in the germination medium), the seeds can be rinsed under tap water in a non-sterile strainer and left to dry preferably in the LFH. Protoplast isolation solution should be sterilized mechanically through Millipore filters with the *PPM*. If the utensil ends have touched active bacteria, fungi culture or otherwise suspected of being contaminated, they should be sterilized by autoclave or by use of an electric heating element.

6. *Endogenous Contamination:*

Plant tissue culture media containing *PPM* at doses of 5-20 ml/l can be used to eliminate endogenous contamination in seeds and plant-explants. In such cases, the seeds or the explants should be mildly surface sterilized, either with 1-5% EPA registered bleach solution plus a few drops of Tween 20, or for 30-60 seconds quick-dip in 70% alcohol, or in a 3% hydrogen peroxide solution. After rinsing with DD water, explants or buds should be embedded or placed in autoclaved semisolid or liquid medium respectively. The proper media such as callus proliferation or regeneration can be used with only ¼ strength of the inorganic salts, supplemented with 5-20 ml/l *PPM*. After 2-5 days the explants can be transferred without rinsing into a similar media (full strength inorganic salts) supplemented with at least 0.5 ml/l *PPM* at 20-24 degrees centigrade. Seeds can be transferred to germination medium (full strength of inorganic salts) supplemented with 0.5 ml/l *PPM* after 5-10 days.

It is up to the researchers to determine the optimal combination of *PPM* doses and time exposure. Different plant types and different explant sources are highly varied in their response to *PPM*.

Storage and Disposal

Storage: Ideal storage temperature is 39°F (4° C). Do not store at temperatures in excess of 70°F (21°C).

Pesticide Disposal: Do not contaminate water, food, or feed by storage and disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility

Container Disposal: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

NET CONTENTS:

PLANT CELL TECHNOLOGY, INC.
1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

Precautionary Statements
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or poison control center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

PPM is a broad-spectrum preservative and biocide. It targets fundamental enzymes in the Krebs cycle and in the Electron Transport Chain. Depending on the dose level, *PPM* is both biocidal (>2ml/L) and biostatic (<2ml/L).

1. Media containing *PPM* may be dispensed outside the laminar flow hood (LFH) exposed to the ambient air. The plates should be covered soon after agar solidification. In the event a pump dispenses the media, we recommend passing autoclaved hot water through the hoses before and after dispensing media.

2. Heat sensitive or heat stable liquid media containing *PPM* do not need to be sterilized by Millipore filters or autoclaved provided that it will be stored in sterile containers and that the stock solutions are not previously contaminated. In rich media containing 200 mg/liter or more of amino acids or proteins, it is recommended to filter the media with the *PPM*.

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1920 N STREET, NW
WASHINGTON, DC 20036

Patent No. 5,750,402

FOR OFFICIAL USE ONLY

FILE SYMBOL	R
REGISTRATION NO.	71806

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

7/9/98

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
7/8/98		

Do Not Write Comments, Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharamacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

PR FORM 9-11
(JULY 1970)

USDA-ARS

Pages 93-102 Confidential Statement of Formula may be entitled to confidential treatment